

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,457	01/05/2001	Anders Larsson	PL-9813	8539
26271 7590 03/09/2006		EXAMINER		
FULBRIGHT & JAWORSKI, LLP			HANDY, DWAYNE K	
1301 MCKINNEY SUITE 5100			ART UNIT	PAPER NUMBER
HOUSTON, T	X 77010-3095		1743	
			DATE MAII ED: 03/09/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)			
	09/674,457	LARSSON ET AL.			
Office Action Summary	Examiner	Art Unit			
	Dwayne K. Handy	1743			
The MAILING DATE of this communication Period for Reply	appears on the cover sheet wi	th the correspondence address			
A SHORTENED STATUTORY PERIOD FOR RE WHICHEVER IS LONGER, FROM THE MAILING - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory per - Failure to reply within the set or extended period for reply will, by state Any reply received by the Office later than three months after the meanned patent term adjustment. See 37 CFR 1.704(b).	B DATE OF THIS COMMUNIC R 1.136(a). In no event, however, may a re- riod will apply and will expire SIX (6) MON' atute, cause the application to become AB.	CATION. eply be timely filed THS from the mailing date of this communication. ANDONED (35 U.S.C. § 133).			
Status					
1) Responsive to communication(s) filed on 20	Responsive to communication(s) filed on 20 December 2005.				
2a) This action is FINAL . 2b) ⊠ T	This action is FINAL . 2b)⊠ This action is non-final.				
	☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is				
closed in accordance with the practice unde	er <i>Ex par</i> te <i>Quayle</i> , 1935 C.D	. 11, 453 O.G. 213.			
Disposition of Claims					
4) Claim(s) 43-49 is/are pending in the application	Claim(s) <u>43-49</u> is/are pending in the application.				
4a) Of the above claim(s) is/are without	4a) Of the above claim(s) is/are withdrawn from consideration.				
5) Claim(s) is/are allowed.	Claim(s) is/are allowed.				
6)⊠ Claim(s) <u>43-49</u> is/are rejected.					
7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction an	d/or election requirement.				
Application Papers					
9) The specification is objected to by the Exam	niner.				
10) The drawing(s) filed on is/are: a) a	☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.				
Applicant may not request that any objection to	the drawing(s) be held in abeyan	ce. See 37 CFR 1.85(a).			
Replacement drawing sheet(s) including the cor	•				
11) ☐ The oath or declaration is objected to by the	Examiner. Note the attached	Office Action or form PTO-152.			
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for fore a) All b) Some * c) None of:	eign priority under 35 U.S.C. §	119(a)-(d) or (f).			
1. Certified copies of the priority docum					
2. Certified copies of the priority docum	ents have been received in A	pplication No			
Copies of the certified copies of the p	priority documents have been	received in this National Stage			
application from the International Bur	, , , , , , , , , , , , , , , , , , , ,				
* See the attached detailed Office action for a	list of the certified copies not	received.			
Amarkananta					
Attachment(s) 1) Notice of References Cited (PTO-892)	A) 🖂 laton i ave S	summary (PTO-413)			
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s	s)/Mail Date			
 Information Disclosure Statement(s) (PTO-1449 or PTO/SB/ Paper No(s)/Mail Date 	/08) 5) Notice of In 6) Other:	nformal Patent Application (PTO-152) —·			

Art Unit: 1743

DETAILED ACTION

1. In view of the Appeal Brief filed on 12/20/05, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

- (1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,
- (2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

Art Unit: 1743

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

- 3. Claims 43-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Kellogg et al. (6,143,248). The Examiner believes Applicant is familiar with the Kellogg reference at this point. The Examiner has reinstated the 102(e) rejection under Kellogg due to the discovery of several missed passages from Kellogg. The Examiner apologizes for the oversight and directs Applicant to columns 8, 10 and 11 of Kellogg. In column 10, line 58 through column 11, line 54, Kellogg recites the following:
- (103) In a fourth embodiment of the invention is provided a centrifugal rotor or Microsystems platform for providing centripetally-motivated fluid micromanipulation, wherein a volume of a fluid sample, most preferably comprising a biological sample, in a first fluid chamber of the rotor or platform is delivered in a stream of droplets into a second fluid chamber on the rotor or platform. In such embodiments of the invention, said rotor or platform is a rotatable platform, comprising a substrate having a first flat, planar surface and a second flat, planar surface opposite thereto, each surface comprising a center about which the platform is rotated. In said centrifugal rotor or microplatform is provided a first surface that comprises the following components in combination:
- (104) 1. An **entry port** comprising a depression in the first surface having a volumetric capacity of about 1 to about 150 .mu.L and that is accessible to an operator for application of a fluid sample, most preferably a fluid comprising a biological sample. The entry port is fluidly connected with
- (105) 2. A first microchannel which defines a cross-sectional area of about 0.02 mm to about 1 mm in diameter that extends radially from the center of the platform and defines a first end proximally arrayed towards the center of the platform and is fluidly connected with the entry port, and a second end distally arrayed from the center of the platform. The first microchannel is further fluidly connected with
- (106) 3. A **first fluid chamber** having a depth in the surface of the platform equal to or greater than the first microchannel and positioned radially more distant from the center of the platform than the entry port. Rotation of the platform at a first rotational speed motivates displacement of the fluid in the entry port through the first microchannel and into the first fluid chamber.
- (107) The platform further comprises:
- (108) 4. A second microchannel, wherein the second microchannel extends radially from the center of the platform and defines a first end proximally arrayed towards the center of the platform and a second end distally arrayed from the center of the platform. The second microchannel is fluidly connected with the first fluid chamber at the first end of the microchannel and the second microchannel is fluidly connected at the second end of the microchannel with
- (109) 5. A **second fluid chamber** having a depth in the surface of the platform equal to or greater than the second microchannel and positioned radially more distant from the center of the platform than the first fluid chamber.

Art Unit: 1743

(110) The second end of the second microchannel comprises a surface that is non-wetting or alternatively the second end of the second microchannel defines an opening into the second fluid reservoir. Rotation of the platform at the first rotation speed does not motivate flow of the displacement fluid through the second microchannel. Rotation of the platform at a second rotational speed that is greater than the first rotational speed motivates flow of the fluid from the first fluid chamber, through the second microchannel and into the second fluid chamber. As a consequence of the properties of the second end of the second microchannel, flow of the fluid into the second fluid chamber comprises a stream of droplets from about 0.1 to about 10 .mu.L in volume. In addition, each of the microchannels and the fluid chambers also comprise air displacement channels whereby air displaced by fluid movement is vented to the surface of the platform.

This passage recites two reservoirs and an entry port connected by two capillary channels on a substrate. The second capillary has a non-wettable portion that blocks fluid flow. Flow past the non-wetting surface in the second end of the second microchannel is achieved by spinning the disk. The embodiment in column 8 recites capillary flow in the channels.

4. Claims 43-47 are also rejected under 35 U.S.C. 102(a) as being anticipated by Kellogg et al. (WO 98/07019). Kellogg (WO 98/07019) recites the same teachings cited from Kellogg ('248).

Inventorship

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

Art Unit: 1743

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

- 6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 7. Claims 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kellogg et al. (6,143,248). Kellogg teaches every element of claims 48 and 49 except for reagents in the liquid sample and a liquid sample between 1-10 nanoliters. It would have been obvious to add reagents to the liquid sample. Kellogg already teaches reagents in the reservoirs of the device. One would add them with the sample in order to allow for longer mixing times. It would have been obvious to use 1-10 nanoliters of sample. One would use smaller amounts of sample to conserve the sample material.

Art Unit: 1743

Response to Arguments

8. Applicant's arguments with respect to the Burns reference have been considered but are most in view of the new ground(s) of rejection.

9. Applicant's arguments filed with respect to the Kellogg reference have been fully considered but they are not persuasive. While the Examiner has changed the rejection under Kellogg the issue of the inlet limitation still remains. Applicant has argued that the instant claims are distinguishable over due to the limitation placed on the inlet: "wherein the inlet is capable of handling less than about 500 nanoliters". Applicant has also stated that the Examiner is relying on beliefs and feelings in characterizing the teachings of Kellogg. The Examiner respectfully disagrees and notes that Applicant has somewhat mischaracterized the Examiner's argument.

The Examiner is relying on the disclosure of Kellogg. Kellogg recites several embodiments of the device having entry ports with a volumetric capacity of 1-100 or 1-150 microliters (column 4, line 10; col. 5, line 56; col. 6, lines 22-23; col. 8, lines 36-37; col. 10, line 33; col. 11, lines 6-7; and col. 11, line 62). These volumetric ranges, when converted to nanoliters, are 1000-100,000 or 1000-150,000 nanoliters.

Therefore, the following is the basis for the Examiner's rejection of the disputed limitation: An entry port having a volumetric capacity of 1000-150,000 or 1000-150,000 nanoliters is inherently capable of handling less than about 500 nanoliters.

The Examiner notes that Applicant has not sufficiently argued this specific issue to overcome the pervious rejection. Applicant has simply claimed that the entry port of

Art Unit: 1743

Kellogg cannot handle amounts on the nanoliter level. Given that the entry port has a greater volume (1000⁺ nanoliters) than that claimed by Applicant (less than about 500 nanoliters), the Examiner fails to see how Kellogg is not capable of handling the 500

nanoliter amount claimed by Applicant.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K. Handy whose telephone number is (571)-

272-1259. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DKH March 6, 2006

Supervisory Patent Examiner
Technology Center 1700